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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,224	07/30/2001	Thomas J. Schall	019934-001710US	5559

20350 7590 10/01/2002

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EXAMINER

BELYAVSKIY, MICHAEL A

ART UNIT	PAPER NUMBER
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1644

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DATE MAILED: 10/01/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/919,224

Applicant(s)

SCHALL ET AL.

Examiner

Michail A Belyavskyi

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1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status**BEST AVAILABLE CO¹**

- 1) ☒ Responsive to communication(s) filed on 30 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-49 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *restriction/Election fax*.

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DETAILED ACTION

Claims 1-49 are pending.

Restriction Requirement

1. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.
2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
 - I. Claims 1, 2 and 4-11, drawn to a method of inhibiting the proliferation of a peripheral blood mononuclear cell population, composing contacting the peripheral blood mononuclear cell with rhesus CMV IL-10 , classified in Class 435, subclass 363.
 - II. Claims 1, and 3-11, drawn to a method of inhibiting the proliferation of a peripheral blood mononuclear cell population, composing contacting the peripheral blood mononuclear cell with human CMV IL-10 , classified in Class 435, subclass 366.
 - III. Claims 12-20, drawn to a method of reducing cytokine production of a monocytes cell population, comprising contacting the monocytes cell population with rhesus CMV IL-10 , classified in Class 435, subclass 363.
 - IV. Claims 12-20, drawn to a method of reducing cytokine production of a monocytes cell population, comprising contacting the monocytes cell population with human CMV IL-10 , classified in Class 435, subclass 366.
 - V. Claims 21-38 , and 44-49 drawn to a method of preventing or treating an immune disorder, comprising administering rhesus CMV IL-10, classified in Class 424, subclass 520.
 - VI. Claims 21-38 , and 44-49 drawn to a method of preventing or treating an immune disorder, comprising administering human CMV IL-10, classified in Class 424, subclass 184.1.

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VII. Claims 39-41, drawn to a method of ameliorating symptoms of hepatitis in an animal host, classified in Class 424, subclass 184.1.

VIII. Claim 42, drawn to a method of preventing or treating a respiratory viral infection, comprising administering rhesus CMV IL-10, classified in Class 424, subclass 520.

IX. Claim 42, drawn to a method of preventing or treating a respiratory viral infection comprising administering human CMV IL-10, classified in Class 424, subclass 184.1.

X. Claim 43, drawn to a method for reducing an in vivo inflammatory response, comprising administering rhesus CMV IL-10, classified in Class 424, subclass 520.

XI. Claim 43, drawn to a method for reducing an in vivo inflammatory response, comprising administering human CMV IL-10, classified in Class 424, subclass 184.1.

4. Groups I- XI are different methods. These inventions are different with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

5. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

Species Election

6. Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

7. If Groups I or II are elected, applicant is required to elect a specific method of inhibiting the proliferation of a peripheral blood mononuclear cell population comprising monitoring secretion of:

A) IFN- γ or

B) TNF- α .

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These species are distinct because the methods of monitoring secretion of IFN- γ or TNF- α differ with respect to the specific test agent and the endpoint of the method; thus each specific method employing a specific test agent represents patentably distinct subject matter.

8. If Groups III or IV are elected, applicant is required to elect a specific method of reducing cytokine production of a monocytes cell, comprising monitoring secretion of specific cytokine, selected from the group recited in claim 20.

These species are distinct because the methods of monitoring secretion of specific cytokine, selected from the group recited in claim 20 differ with respect to the specific test agent and the endpoint of the method; thus each specific method employing a specific test agent represents patentably distinct subject matter.

9. If Groups V or VI are elected, applicant is required to elect a specific method of preventing or treating specific immune disorder, wherein an immune disorder selected from the group recited in claim 24.

These species are distinct because method of preventing or treating specific immune disorder, differ in etiologies and therapeutic endpoints of pathological conditions; thus each condition represents patentably distinct subject matter.

In addition, applicant is required to elect a specific method of preventing or treating specific chronic inflammatory disease, wherein specific chronic inflammatory disease selected from the group recited in claims 33 and 49.

These species are distinct because method of preventing or treating specific chronic inflammatory disease differ in etiologies and therapeutic endpoints of pathological conditions; thus each condition represents patentably distinct subject matter.

In addition, applicant is required to elect a specific method of preventing or treating specific immune disorder in patient wherein patient is suffering from a type T_H1 immune response to a specific transplant graft organ selected from the group recited in claim 37.

These species are distinct because specific method of preventing or treating specific immune disorder in patient wherein patient is suffering from a type T_H1 immune response to a specific transplant graft organ selected from the group recited in claim 37 differ in etiologies and therapeutic endpoints of pathological conditions; thus each condition represents patentably distinct subject matter.

10. If Group VII is elected, applicant is required to elect a specific method of ameliorating symptoms of hepatitis in an animal host, wherein the administering step ameliorates :

A) liver disease or,

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B) liver fibrosis.

These species are distinct because a specific method of ameliorating symptoms of hepatitis in an animal host, wherein the administering step ameliorates liver disease or liver fibrosis differ in etiologies and therapeutic endpoints of pathological conditions; thus each condition represents patentably distinct subject matter.

11. If Groups X or XI are elected, applicant is required to elect a specific method for reducing an in vivo inflammatory response characterized by substantially elevated levels of at least one specific cytokine selected from the group recited in the claim 43.

These species are distinct because the methods for reducing an in vivo inflammatory response characterized by substantially elevated levels of at least one specific cytokine selected from the group recited in the claim 43 differ with respect to the specific test agent and the endpoint of the method; thus each specific method employing a specific test agent represents patentably distinct subject matter.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

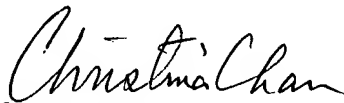
12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskiy, Ph.D.
Patent Examiner
Technology Center 1600
October 1, 2002


CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600